IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

RECKITT BENCKISER PHARMACEUTICALS, INC., RB PHARMACEUTICALS LIMITED, and MONOSOL RX, LLC, Plaintiffs, v. ALVOGEN PINE BROOK, INC. Defendants.	)	CA. No. 13-CV-2003 RGA

FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Reckitt Benckiser Pharmaceuticals, Inc. ("RBP"), RB Pharmaceuticals Limited ("RBP UK"), and MonoSol Rx, LLC ("MonoSol") (collectively, "Plaintiffs") file this Amended Complaint against Defendant Alvogen Pine Brook, Inc. ("Alvogen PB" or "Defendant") pursuant to Fed. R. Civ. P 15(a)(2) and Defendant's written consent (*see* D.I. 18, D.I. 19), and allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the Food and Drug Laws and Patent Laws of the United States, Titles 21 and 35 of the United States Code, respectively, arising from Defendant Alvogen PB's submission of an Abbreviated New Drug Application ("ANDA") to the Food and Drug Administration ("FDA") seeking approval to manufacture, use, and sell a generic version of Plaintiff RBP's Suboxone® sublingual film prior to the expiration of United States Patent Nos. 8,475,832 ("the '832 patent") and 8,017,150 ("the '150 patent"), and 8,603,514 ("the '514 patent") (collectively, "the patents-in-suit").

THE PARTIES

2. Plaintiff RBP is a Delaware corporation having a principal place of business at 10710 Midlothian Turnpike, Suite 430, Richmond, Virginia.

3. Plaintiff RBP UK is a United Kingdom corporation having a principal place of business at 103-105 Bath Road, Slough, UK.

4. Plaintiff MonoSol is a Delaware limited liability corporation having a principal place of business at 30 Technology Drive, Warren, New Jersey.

5. On information and belief, Defendant Alvogen PB is a Delaware corporation having a principal place of business at 10 Bloomfield Avenue, Building B, Pine Brook, New Jersey.

6. On information and belief, Alvogen PB is a subsidiary of Alvogen Group, Inc.

JURISDICTION AND VENUE

7. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

8. This Court has personal jurisdiction over Alvogen PB because Alvogen PB is incorporated in Delaware, has previously submitted to the jurisdiction of this judicial district, and engages in marketing and sales activities in this judicial district, including, but not limited to, the substantial, continuous, and systematic marketing and/or selling of generic pharmaceutical products to residents of this judicial district.

9. Venue is proper in this district under 28 U.S.C. §§ 1391 and 1400.

THE PATENTS-IN-SUIT

10. Plaintiff RBP UK is the lawful owner of the ’832 patent. The ’832 patent, entitled “Sublingual and Buccal Film Compositions,” duly and legally issued on July 2, 2013, naming Garry L. Myers, Samuel D. Hillbert, Bill J. Boone, B. Arlie Bogue, Pradeep Sanghvi, and

Madhusudan Hariharan as inventors. A true copy of the '832 patent is attached hereto as Exhibit A.

11. Plaintiff MonoSol is the lawful owner of the '150 patent, and Plaintiff RBP is an exclusive licensee of the '150 patent. The '150 patent, entitled "Polyethylene Oxide-Based Films and Drug Delivery Systems Made Therefrom," duly and legally issued on September 13, 2011, naming Robert K. Yang, Richard C. Fuisz, Garry L. Myers, and Joseph M. Fuisz as inventors. A true copy of the '150 patent is attached hereto as Exhibit B.

12. Plaintiff MonoSol is the lawful owner of the '514 patent, and Plaintiff RBP is an exclusive licensee of the '514 patent. The '514 patent, entitled "Uniform Films for Rapid Dissolve Dosage Forms Incorporating Taste-Masking Compositions," duly and legally issued on December 10, 2013, naming Robert K. Yang, Richard C. Fuisz, Garry L. Myers, and Joseph M. Fuisz as inventors. A true copy of the '514 patent is attached hereto as Exhibit C.

SUBOXONE® SUBLINGUAL FILM

13. Plaintiff RBP is the holder of New Drug Application ("NDA") No. 22-410 for Suboxone® (buprenorphine hydrochloride and naloxone hydrochloride) sublingual film.

14. On August 30, 2010, the FDA approved NDA No. 22-410 for the manufacture, marketing, and sale of Suboxone® sublingual film for the maintenance treatment of opioid dependence. Plaintiff RBP has sold Suboxone® sublingual film under NDA No. 22-410 since its approval.

15. The patents-in-suit are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") as covering Suboxone® sublingual film.

DEFENDANT'S ANDA

16. Plaintiffs received letters from "Alvogen" dated October 25, 2013 and November 21, 2013 (the "Notification Letters"), stating that ANDA No. 205954 contains a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "Paragraph IV certification") alleging that the '832 and '150 patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of the generic product proposed in the ANDA.

17. The Notification Letters further state that Alvogen PB submitted ANDA No. 205954 to the FDA under 21 U.S.C. § 355(j), seeking approval to engage in commercial manufacture, use, or sale of buprenorphine and naloxone sublingual film ("Defendant's generic product") before expiration of the patents-in-suit. On information and belief, ANDA No. 205954 refers to and relies on Plaintiff RBP's NDA for Suboxone® sublingual film and purports to contain data showing bioequivalence of Defendant's generic product with Suboxone® sublingual film.

18. Plaintiffs commenced this action within 45 days of receiving the Notification Letter dated October 25, 2013.

19. Plaintiffs received another letter from "Alvogen" dated December 10, 2013 (the "'514 Notification Letter"), stating that ANDA No. 205954 contains a Paragraph IV certification alleging that the '514 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of the generic product proposed in the ANDA.

20. The '514 Notification Letter further states that ANDA No. 205954 seeks approval for Alvogen to engage in commercial manufacture, use, or sale Defendant's generic product before expiration of the '514 patent. On information and belief, ANDA No. 205954 refers to and

relies on Plaintiff RBP's NDA for Suboxone® sublingual film and purports to contain data showing bioequivalence of Defendant's generic product with Suboxone® sublingual film.

21. Plaintiffs have subsequently received additional letters identical to the '514 Notification Letter.

22. Plaintiffs filed this Amended Complaint within 45 days of receiving the '514 Notification Letter.

COUNT I
(Infringement of the '832 Patent Under 35 U.S.C. § 271(e)(2))

23. Plaintiffs reallege paragraphs 1-22 above as if fully set forth herein.

24. On information and belief, Defendant's generic product is covered by one or more claims of the '832 patent.

25. By filing ANDA No. 205954 under 21 U.S.C. § 355(j) for the purposes of obtaining approval to engage in the commercial manufacture, use, or sale of Defendant's generic product prior to the expiration of the '832 patent, Defendant has committed an act of infringement of the '832 patent under 35 U.S.C. § 271(e)(2).

26. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for ANDA No. 205954 to be a date which is not any earlier than the expiration date of the '832 patent, including any extensions of that date.

COUNT II
(Infringement of the '150 Patent Under 35 U.S.C. § 271(e)(2))

27. Plaintiffs reallege paragraphs 1-26 above as if fully set forth herein.

28. On information and belief, Defendant's generic product is covered by one or more claims of the '150 patent.

29. By filing ANDA No. 205954 under 21 U.S.C. § 355(j) for the purposes of obtaining approval to engage in the commercial manufacture, use, sale and/or importation of Defendant's generic product prior to the expiration of the '150 patent, Defendant has committed an act of infringement of the '150 patent under 35 U.S.C. § 271(e)(2).

30. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for ANDA No. 205954 to be a date which is not any earlier than the expiration date of the '150 patent, including any extensions of that date.

COUNT III
(Infringement of the '514 Patent Under 35 U.S.C. § 271(e)(2))

31. Plaintiffs reallege paragraphs 1-30 above as if fully set forth herein.

32. On information and belief, Defendant's generic product is covered by one or more claims of the '514 patent.

33. By filing ANDA No. 205954 under 21 U.S.C. § 355(j) for the purposes of obtaining approval to engage in the commercial manufacture, use, sale and/or importation of Defendant's generic product prior to the expiration of the '514 patent, Defendant has committed an act of infringement of the '514 patent under 35 U.S.C. § 271(e)(2).

34. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for ANDA No. 20-5954 to be a date which is not any earlier than the expiration date of the '514 patent, including any extensions of that date.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court enter:

A. A judgment that Defendant has infringed each of the patents-in-suit under 35 U.S.C. § 271(e)(2) by submitting and maintaining ANDA No. 205954;

B. Preliminary and permanent injunctions, restraining and enjoining Defendants, their officers, agents, attorneys, affiliates, divisions, successors and employees, and those acting in privity or concert with them, from engaging in, causing, or inducing the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of drugs and formulations, or from inducing and/or encouraging the use of methods, claimed in the patents-in-suit;

C. An order that the effective date of any approval of ANDA No. 205954 be a date that is not earlier than the expiration of the last to expire of the patents-in-suit, including any extensions thereof and any later expiration of exclusivity associated with those patents;

D. A judgment and order finding that this is an exceptional case within the meaning of 35 U.S.C. § 285 and awarding to Plaintiffs their reasonable attorneys' fees;

E. A judgment granting Plaintiffs compensatory damages in an amount to be determined at trial including both pre-judgment and post-judgment interest if Defendants commercially manufacture, use, offer to sell, or sell in the United States, or imports into the United States, Defendant's generic product before the expiration of each patent-in-suit that Defendants are found to infringe, including any extensions; and

F. Any and all other relief as the Court deems just and proper.

Dated: January 24, 2014

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on January 24, 2014, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF which will send electronic notification of such filing to all registered participants.

Additionally, I hereby certify that true and correct copies of the foregoing were caused to be served on January 24, 2014, upon the following individuals via electronic mail:

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